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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,490	10/11/2001	Koh Kimura	14991	9704

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EXAMINER

PANTUCK, BRADFORD C

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 08/07/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/975,490	KIMURA ET AL.
Examiner	Art Unit	
Bradford C Pantuck	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 11 October 2001.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-56 is/are pending in the application.

4a) Of the above claim(s) 41-56 is/are withdrawn from consideration.

5) Claim(s) 1-6 and 9-16 is/are allowed.

6) Claim(s) 7,17-22,25,28-30 and 32-40 is/are rejected.

7) Claim(s) 8, 23, 24, 26, 27, and 31 is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 11 October 2001 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3, 5, 6</u> .	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group 1, Claims 1-40, in Paper No. 8 is acknowledged.

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the holding means engaging with the tightening ring, as detailed in Claim 33, must be shown or the feature(s) canceled from the claim(s). It is unclear what the Applicant means in Claim 33 by the holding means being a step, which engages the tightening ring. The drawings do not show this feature. No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

2. Claim 38 is objected to because of the following informalities: in line 2 of Claim 38, the phrase "said clip an be elastically" has a misspelling. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 7, 8, 26 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention: the clause "sealing these clip, tightening ring, and link member, ..." is grammatically incorrect which causes the meaning to be obscured. The plural pronoun "these" must be followed with a plural noun. In order to be consistent with the rest of the sentence, "tightening ring" should be preceded with a definite article. Also, the clause starting "while said link member..." and finishing with "...on said link member" is placed strangely in the sentence and causes the Claim to be confusing. Appropriate correction is required.

4. Claim 32 recites the limitation "the arms" in line 3. There is insufficient antecedent basis for this limitation in the claim. It cannot be assumed that a clip necessarily has arms. For example, a member resembling a spring could be used as a clip.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 17-22, 25, 28-30, and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,766,189 to Matsuno. Regarding Claims 17, 19, and

25 Matsuno discloses a clip (2) capable of being arbitrarily opened and closed. He also discloses a tightening ring (4) engagingly mounted on the clip (2), closing the clip [Column 2, lines 63-65]. Matsuno discloses a link member (3) capable of being inserted into the tightening ring and engaged with the clip (2) [see Fig. 4]. Further, Matsuno discloses a manipulating wire (13) with a hook (15) at its distal end [Column 5, lines 12-18; Fig. 6]. The link member (3) is set at an arbitrary circumferential position relevant to an axial direction of the hook (25). The link member and hook are engaged with each other [see Fig. 8]. The link member is deformed, as shown in Figure 7, and described in Column 5, lines 58-63. Although Matsuno singles out component (3A) of his link member (3) as stretching and deforming elastically, the whole member (3) is made out of one material [metal] and the *whole member will stretch and deform elastically to some degree* [Column 3, lines 26-28; Column 4, lines 11-16].

6. Regarding Claims 18 and 20, Matsuno discloses a clipping apparatus with deformation means provided at the hook (15). The hook is particularly suited for deformation at the thin stem part (17) of the hook, where it is less thick than the top portion (16) of the hook [Column 4 line 66-Column 5 line 2]. The thin portion of the hook is *capable of* deformation. Therefore, as explained in the two paragraphs above, deformation means are provided at the link member *and* the hook, as stated in Claim 20.
7. Regarding Claim 21, Matsuno discloses an apparatus with a hook (15) having an arm section (17) and a pinch section (16). Matsuno's arm section can be used to

close another component of the device. Also, Matsuno's pinch section pinches and fixes a proximal part of the link member (3).

8. Regarding Claim 22, Matsuno's arm section (proximal end of component 3) can be used to close another component of the device. Also, Matsuno's arm section is able to pinch and fix a distal part of the hook member (15) [see Fig. 9A]. The arm section is the curved section at the proximal end of the link member (3) [see Fig. 9A].

9. Regarding Claim 28, in addition to a clip (2), a tightening ring (4), and a link member (3), Matsuno's clipping apparatus includes a holding means for temporarily holding the clip in its maximum opened state. The holding means is the inner surface of component (7), and as can be seen in Figure 6, the inner surface of component (7) and the inner surface of the tightening ring (4) hold the clip in its maximum opened state. During the process of clipping, the clip does not become more open than it is shown in Figure 6, and therefore the state shown in Figure 6 is considered to be the maximum opened state of the clip.

10. Regarding Claim 29, the holding means is provided at the clip—i.e. the holding means [inner surface of components 7 and 4] is contiguous to the clip.

11. Regarding Claim 30, the holding means is provided at the tightening ring—i.e. the holding means [inner surface of components 7] is contiguous to the tightening ring. The tightening ring has its inner surface in common with the inner surface of component 7.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this

subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claim 34 is rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,402,765 to Monassevitch et al. Monassevitch discloses a physiological tissue clip (170) capable of being arbitrarily opened and closed, which is made out of a super-elastic alloy. In fact, Monassevitch teaches making the entire device out a super-elastic material [Column 7, lines 25-28]. Monassevitch discloses a tightening ring (142/144) mounted on both components of the clip (172/174). The tightening ring (142/144) closes the clip [Column 8, lines 15-22]. A link member (180) is inserted into the bottom tightening ring (144) when the clip (172/174 closes)—i.e. it advances into and through the interior of ring (144).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over 5,766,189 to Matsuno in view of U.S. Patent No. 5,207,692 to Kraus et al. Matsuno discloses the invention as claimed, excepting the holding means as a step that is provided at each of the arms of the clip. However, Kraus teaches that one would have steps (70/74) as holding means on each of the arms of a surgical clip in order to limit

the amount that the jaws can open [Column 9, lines 32-38]. The steps move into engagement with each other, and temporarily hold the clip in an opened state. That is, if one tries to open the jaws from the position shown in Figure 8, the steps (70/74) will prevent the jaws from moving, *maintaining the jaws in the opened state* show in Figure 8. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to apply the concept of having steps on arms, as taught by Kraus, in order to maintain the jaws of a clip in a specific opened state

Regarding Claim 33, as best understood, the apparatus of Matsuno as modified by Kraus has holding means that is a step that is provided at each of the arms of the clip that is engaged with the tightening ring.

14. Claims 34-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,766,189 to Matsuno in view of U.S. Patent No. 6,402,765 to Monassevitch et al. Regarding Claims 34 and 40, Matsuno discloses the invention as claimed (as described above) except that his clip is not a super-elastic alloy. However, Monassevitch teaches that one would make a surgical clip for clipping tissue out of shape memory material in order to enable portions of tissue to be pressed together when body temperature is reached (but not before then). He also teaches that surgical clips made out of super-elastic materials are easy to design and are inexpensive to manufacture [Column 1, lines 38-47]. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to make

Matsuno's clip out of a super elastic alloy in order to allow the target tissues to be clamped *upon the reaching of the body temperature.*

15. Regarding Claim 35, Matsuno's modified clip is bent at its center portion. Additionally, the modified clip has an opening width capable of ligating physiological tissue [see Fig. 5]. In fact, the purpose of the device is to clip tissue [Column 1, lines 5-8].
16. Regarding Claim 37, Matsuno's clip can be elastically deformed/restored from a closed state capable of being housed in a forceps channel [see Fig. 5] of an endoscope to an opened state [see Fig. 6] capable of ligating tissue.
17. Regarding Claim 39, the Matsuno's clip, as modified by Monassevitch, is composed of a planar super-elastic alloy. Figure 4 shows the clip (2), which has particularly planar end portions.
18. Regarding Claims 36, Matsuno's clip, as modified by Monassevitch, opens to a width necessary to ligate tissue of various types [Column 1, lines 5-8]. However, Monassevitch does not disclose the exact proportions of his clip's arms and opening distance. However, Nash discloses a clip (20) for ligating body tissue with an *arm length of 17.8 mm* [see Fig. 1; Column 6, lines 13-19]. Nash also discloses that his clip has a width of 4.57 mm, and comparing the width of the clip shown in Figure 3 with the opening width of the clip shown in Figure 4, it is clear that the opened width of Nash's clip is about 4.5 mm. Nash explains that his clip has such small proportions so that so that it can be applied through a very small incision, using a tool

with a 5 mm sheath for use in endoscopic surgery [Column 2, lines 5-11; Column 6, lines 14-20]. Nash's surgical procedure allows the surgeon to not make an incision with a trocar, which is beneficial to patient [Column 1 line 63 to Column 2 line 2]. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention make the proportions of the modified Matsuno clip to the specifications (dimensions) prescribed by Nash so as to be able to insert the clip through a very small incision in the body, and thus avoid the use of a trocar.

19. Regarding Claim 38, it would have been obvious to one of ordinary skill in the art at the time of the invention to make the modified Matsuno clip capable of being housed in a 3 mm cavity instead of a 5 mm cavity (as taught by Nash), as a matter of mere design choice. The Applicant does not disclose a reason for having the cavity sized 3 mm, and therefore it would have been obvious to make the clip a little smaller so as to be able to fit inside a 3 mm cavity.

Allowable Subject Matter

20. Claims 1-6 and 9-16 are allowed.

The following is an examiner's statement of reasons for allowance: Regarding Claim 1, the phrase "disabling the tightening ring from being housed again in the introducing tube" implies that *the tightening ring was at one time inside the introducing tube*.

Regarding Claim 9, None of the prior art of record, alone or in combination, discloses a surgical clip with a tightening ring, a link member, an introducing tube, a

manipulating member, and *a cover provided on the clip capable of entering an opened state*, as set forth by the applicant.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

21. Claim 8 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 5,520,701 to Lerch

U.S. Patent No. 5,993,465 to Shipp et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (703) 305-8621. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on (703) 308-2496. The fax phone numbers for the

Art Unit: 3731

organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

BCP

August 1, 2003



MICHAEL J. MILANO
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